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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,171

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Taeko Iino

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EXAMINER

HENRY, MICHAEL C

ART UNIT

PAPER NUMBER

1623

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/561,171	<b>Applicant(s)</b> IINO ET AL.	
	<b>Examiner</b> MICHAEL C. HENRY	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09/18/07.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13 and 16-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13 and 16-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/18/07</u> .                                                | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The following office action is a responsive to the Amendment filed, 09/18/07.

The amendment filed 09/18/07 affects the application, 10/561,171 as follows:

1. Claims 13, 16-24 have been amended. Claims 1-12, 14-15, 25-36 have been canceled. New Claims 25-26 have been added.
2. The responsive to applicants' arguments is contained herein below. Claims 13, 16-26 are pending in the application

#### ***Claim Objections***

Claims 25 and 26 are objected to because of the following informalities: The claims are incorrectly indexed or numbered since claims 25 and 26 were canceled. This appears to be a typographical error since these claims are the last claims listed. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-18, 20, 23, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. (US 6,372,266).

In claim 13, applicant claims a method for reducing muscular fatigue, comprising administering proanthocyanidin a human being in an amount effective to reduce muscular fatigue. Claim 16 is drawn to a method for reducing fatigue comprising administering a health

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food containing proanthocyanidin as an effective ingredient to a human being. Claims 17-24 are drawn to said method wherein the health food is in specific forms including solid food, beverage, tablet and wherein the proanthocyanidin is an extract derived from pine bark or is an oligomeric proanthocyanidin. Claims 25 and 26 are drawn to said method wherein lactic acid buildup upon physical exercise is reduced.

Suzuki et al. disclose that a composition comprising a pine bark extract and containing proanthocyanidins as an effective component thereof can be administered to a humans to treat leg cramps (i.e., sudden, involuntary, spasmodic muscular contraction causing severe pain) and chronic fatigue syndrome (CFS) (see col. 2, line 20 to col. 3, line 8). Furthermore, Suzuki et al. disclose that the composition is widely used as a nutritional supplement food (see col. 2, lines 20-26). Furthermore, Suzuki et al. disclose that pine bark extract and containing proanthocyanidins can be in the form of tablets, liquid and powdery preparations (see col. 2, lines 1-11; col. 4, lines 35-40 and abstract). Suzuki et al. disclose a method for treating dysmenorrhea (which is the occurrence of painful cramps which are sudden, involuntary, spasmodic muscular contractions causing severe pain) during menstruation, characterized in that proanthocyanidin is administered to a human (see abstract). It should also be noted that muscular fatigue and myalgia (muscle pain) are associated with Chronic Fatigue Syndrome (CFS) (see Exhibit A attached, <http://www.immunesupport.com/chronic-fatigue-syndrome-causes.htm>). Also, it should be noted that Chronic fatigue and immune dysfunction syndrome (abbreviated CFIDS or CFS) is a group of symptoms associated with severe, almost unrelenting fatigue. It should be noted that it is known that muscular cramps (e.g., a leg cramp) are

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associated with muscular fatigue and shortened muscle contraction (see e.g. Exhibits B as attached).

The difference between applicant's claimed method and the method of Suzuki et al. is that Suzuki et al. do not exemplify the treatment or reduction of muscular fatigue by administering the composition to said human. However, Suzuki et al. disclose that Chronic fatigue syndrome and leg cramps can be treated by administering their composition containing proanthocyanidin to a human being and consequently a skilled artisan would be motivated to treat fatigue such as muscular fatigue in said human since Suzuki et al. disclose that Chronic fatigue syndrome can be treated and especially since it is known that muscular fatigue is associated with Chronic Fatigue Syndrome (CFS). Also, the fact that it is known that muscular cramps (e.g., a leg cramp) are associated with muscular fatigue and shortened muscle contraction provides even greater motivation to a skilled artisan to treat muscular fatigue in said human with said proanthocyanidin composition.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to treat or reduce muscular fatigue by administering Suzuki et al.'s composition containing proanthocyanidin to a human, since Suzuki et al. disclose that pine bark extract containing proanthocyanidins as an effective component can be administered to a humans to treat chronic fatigue syndrome and leg cramps and especially since it is known that muscular fatigue is associated with Chronic Fatigue Syndrome (CFS) and muscular cramps (e.g., a leg cramp) are associated with muscular fatigue.

One having ordinary skill in the art would have been motivated, to treat or reduce muscular fatigue by administering Suzuki et al.'s composition containing proanthocyanidin to a

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human, since Suzuki et al. disclose that pine bark extract containing proanthocyanidins as an effective component can be administered to a humans to treat chronic fatigue syndrome and leg cramps and especially since it is known that muscular fatigue is associated with Chronic Fatigue Syndrome (CFS) and muscular cramps (e.g., a leg cramp) are associated with muscular fatigue.

### ***Response to Arguments***

Applicant's arguments with respect to claims 13, 16-26 have been considered but are not found convincing.

The applicant argues that leg cramps and CFS are not examples of muscular fatigue. However, it should also be noted that muscular fatigue and myalgia (muscle pain) are associated with Chronic Fatigue Syndrome (CFS) (see Appendix A, <http://www.immunesupport.com/chronic-fatigue-syndrome-causes.htm>). Also, it should be noted that Chronic fatigue and immune dysfunction syndrome (abbreviated CFIDS or CFS) is a group of symptoms associated with severe, almost unrelenting fatigue. In addition, it should be noted that it is known that muscular cramps (e.g., a leg cramp) are associated with muscular fatigue and shortened muscle contraction (see e.g. Exhibits B). Furthermore, Suzuki et al. disclose that Chronic fatigue syndrome and leg cramps can be treated by administering their composition containing proanthocyanidin to a human being and consequently a skilled artisan would be motivated to treat fatigue such as muscular fatigue in said human since Suzuki et al. disclose that Chronic fatigue syndrome can be treated and especially since it is known that muscular fatigue is associated with Chronic Fatigue Syndrome (CFS). Also, the fact that it is known that muscular cramps (e.g., a leg cramp) are associated with muscular fatigue and

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shortened muscle contraction provides even greater motivation to a skilled artisan to treat muscular fatigue in said human with said composition (see the attached Exhibits A &B).

The applicant argues that in the presently claimed invention, “lactic acid buildup upon physical exercise is reduced.” Proanthocyanidin advantageously suppresses the rise in lactic acid value upon physical exercise, making continuous and effective physical exercise easy. However, examiner considers the reduction of said lactic acid the mechanism by which said muscular fatigue is treated.

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the

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examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

Shaojia Anna Jiang, Ph.D.  
Supervisory Patent Examiner  
Art Unit 1623

/Shaojia Anna Jiang/  
Supervisory Patent Examiner, Art Unit 1623  
February 19, 2008.